



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,753	01/02/2002	Stanley Hazen	26473/04177	9142
24024	7590	08/17/2006	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/039,753	HAZEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 July 2006.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10,23,25,26,28,29 and 31-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 31 and 33 is/are allowed.

6) Claim(s) 1-10,23,25,26,28,29 and 32 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

Art Unit: 1644

The After Final Amendment of 7/26/06 has been entered. Claims 1-10,23,25-26,28-29,31-33 are pending. Claims 1-10, 23,25-26,28-29,31-33 are under examination. The examiner has rejoined claims 2-6, since the limitations concerning myeloperoxidase activity were previously examined in claim 28.

The amendment has entered no new matter.

The amendment has overcome previously stated issues as follows:

The prior art rejections based upon Minota et al.

Upon reconsideration the following grounds of rejection are newly stated.

Claims 1-10,23,25-26,28-29,32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the embodiment in which blood leukocytes are selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereof, does not reasonably provide enablement for the embodiment in which blood leukocytes are selected from the group consisting of neutrophils, monocytes, mononuclear lymphocytes, sub-populations of neutrophils, sub-populations of monocytes, and sub-populations of mononuclear lymphocytes, or any combination thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Pat 5,871,946 teaches that lymphocytes do not show peroxidase activity, while monocytes and neutrophils do show peroxidase activity. See col. 34, lines 13+. Since it is art recognized that lymphocytes do not show peroxidase activity and since applicant has shown no exemplification to the contrary, any claimed method that encompasses determining the level of MPO in leukocytes that are lymphocytes or a sub-population thereof is overly broad in scope.

Claims 1,3,5-8,10,23,26,29 are rejected under 35 U.S.C. 102(a) as anticipated by Or, alternatetivly, under 35 U.S.C. 103(a) as obvious over Zhang et al (JAMA, 286, 2136, 2001,cited on Form 1449).

The rejection is proper since the reference has a 102(a) date and has authors who are not inventors. Applicant may overcome by filing a Rule 132 declaration in accord with In re Katz 215 USPQ 14.

The reference has a 102(a) date because the instant claims are only accorded benefit of the instant filing date of 1/2/02. The examiner finds that the instant claims are broader than the invention supported by the last filed provisional application 60/283,432. The claims are thus properly rejected in accord with MPEP 201.11. Claims are deemed broader because of at least the following features:

1) the nature of the controls. In the '432 application the controls are limited to "healthy controls". There is no teaching of controls from the "general population" and there is no teaching of any "select population of controls" other than "healthy controls".

2) the nature of the sample. In the '432 application the "leukocytes" are limited to neutrophils or monocytes (p 2, last para.). There is no teaching of "lymphocytes" or of any "sub-populations" of neutrophils, monocytes or lymphocytes, or of any "combinations thereof".

Zhang et al teach determining myeloperoxidase (MPO) mass per neutrophils (and thus a "normalized" value) by an ELISA ("immunological") assay. See para. spanning pp 2137-2138. Zhang et al also teach determining the MPO activity of lysed neutrophils, normalized as per mg of neutrophils protein or as per mg of blood. See p 2137, para spanning cols. 2-3. They compare levels of MPO (mass or activity) in patients having angiographically proven coronary atherosclerosis against a "select population" of control patients that showed no such diagnosed atherosclerosis. See p 2137, col. 1 and p 2141, col.1. They conclude that "MPO levels are associated with the presence angiographically proven coronary atherosclerosis." See p 2141, col.1, last para. Thus instant claims 1, 3, 5-8, 10 and 23 are anticipated for the embodiment in

Art Unit: 1644

which the claimed method characterizes a patient as "having atherosclerotic cardiovascular disease". Zhang et al also teach that further studies should be conducted to evaluate "MPO as a predictor of future cardiac events in longitudinal studies". Thus instant claims 1, 3, 5-8, 10, 23, 26 and 29 would have been obvious for the embodiment in which the claimed method characterizes a patient as at "risk of developing... atherosclerotic cardiovascular disease".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 8/14/06 DAS

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 1644